Laparoscopic Adjustable Silicone Gastric Banding Versus Vertical Banded Gastroplasty in Morbidly Obese Patients

A Prospective Randomized Controlled Clinical Trial

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Objective: To compare, in a prospective, randomized, single-institution trial laparoscopic adjustable silicone gastric banding (LASGB) with laparoscopic vertical banded gastroplasty (LVBG) in morbidly obese patients.

Summary Background Data: LASGB is a simple and safe procedure, but some reports have suggested disappointing long-term results. Despite the recent widespread use of LASGB, there are no prospective nor randomized trials comparing LASGB with other laparoscopic procedures.

Methods: A total of 100 morbidly obese patients, with body mass index (BMI) 40 to 50 kg/m^2, without compulsive eating, were randomized to either LASGB (n = 49) or LVBG (n = 51). Minimum follow-up was 2 years (mean 33.1 months).

Results: There were no deaths or conversions in either group. Mean operative time was 94.2 minutes in LVBGs and 65.4 in LASGBs ($P < 0.05$). Early morbidity rate was lower in LASGBs (6.1%) versus LVBGs (9.8%) ($P = 0.754$). Mean hospital stay was shorter in LASGBs versus LVBGs: 3.7 days versus 6.6 ($P < 0.05$). Late complications rate in LVBGs was 14% (7 of 50) and in LASGBs 32.7% (16 of 49) ($P < 0.05$). The most frequent complication was the slippage of the band (18%). Late reoperations rate in LVBGs was 0% (0 of 50) versus 24.5% (12 of 49) in LASGBs ($P < 0.001$). Excess weight loss in LVBGs was, at 2 years, 63.5% and, at 3 years, 58.9%; in LASGBs, excess weight loss, respectively, was 41.4% and 39%. BMI in LVBGs was, at 2 years, 29.7 kg/m^2 and, at 3 years, 30.7 kg/m^2; in LASGBs, BMI was 34.8 kg/m^2 at 2 years and 35.7 kg/m^2 at 3 years. According to Reinhold's classification, a residual excess weight <50% was achieved, at 2 years, in 74% of LVBG and 35% of LASGB ($P < 0.001$).

Conclusions: This study demonstrates that, in patients with BMI 40 to 50 kg/m^2, LASGB requires shorter operative time and hospital stay but LVBG is more effective in terms of late complications, reoperations, and weight loss.

(*Ann Surg* 2003;238: 835–842)

The introduction of laparoscopic surgery has created a revolution in the field of bariatric surgery. Laparoscopic procedures have progressively replaced traditional open bariatric procedures in both Europe and North America. Although gastric bypass[1–3] and duodenal switch[4] currently represent 80% of laparoscopic bariatric procedures in the United States and Canada,[5] in Europe laparoscopic gastric restrictive procedures still represent the majority of bariatric procedures.[6,7] Two reasons explain this disparity. First, different diet habits lead to a better response in European patients following gastric restrictive procedures. Second, most European patients present for bariatric surgery with a body mass index (BMI) between 35 and 50 kg/m^2, and superobese patients (BMI >50 kg/m^2) remain a rare entity. Gastric restrictive procedures frequently fail in the superobese patient population.[8,9]

Laparoscopic adjustable silicone gastric banding (LASGB) was the first bariatric procedure to be performed by a laparoscopic approach.[10–12] Introduction of LASGB into clinical practice was an immediate success. It caused the rapid growth of bariatric programs in surgical departments throughout European countries, where these procedures were limited to a few centers in the past. Despite the recent widespread use of LASGB, long-term outcome evidence is limited.[13]

Moreover, few studies provide precise data for long-term follow-up.[14–16] Some studies even report disappointing long-term results.[17,18] To the best of our knowledge, there are no prospective studies or randomized controlled trials comparing LASGB to other laparoscopic bariatric procedures.

The randomized trial published by Nilsell et al,[19] comparing adjustable gastric banding and vertical banded gastroplasty (VBG), was related to open procedures. To date,

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0003-4932/03/23806-0835

DOI: 10.1097/01.sla.0000098627.18574.72

randomized controlled trials have addressed different technical variations of one laparoscopic bariatric procedure,[20] or they have compared the traditional open approach with a minimally invasive approach for the same procedure.[21–23] To fully validate LASGB, we must gauge it against other restrictive laparoscopic procedures. The aim of this study is to compare LASGB with laparoscopic vertical banded gastroplasty (LVBG). LVBG was the most popular gastric restrictive procedure during the prelaparoscopic era. In our experience, LVBG continues to provide satisfactory outcomes when performed with a minimally invasive approach.[24] Therefore, it is appropriate for comparison with LASGB.

MATERIALS AND METHODS

A prospective randomized controlled trial was created. Prior to start of the study, approval was obtained from the hospital ethics committee. Patient inclusion criteria included: history of obesity $\geq$ 5 years, documented weight loss attempts in the past, BMI from 40 to 50 kg/m^2, and age between 18 and 60 years. Exclusion criteria included: contraindications to creation of pneumoperitoneum (eg, glaucoma), large esophageal hiatal hernias (>3 cm), symptomatic gastroesophageal reflux disease, pregnancy, drug or alcohol abuse, psychologic disorders (eg, bulimia, depression), hormonal or genetic obesity-related disease, and previous gastric surgery.

Patients were evaluated by a dietician to exclude concentrated "sweet" eaters and "binge" eaters. These two groups of patients represent a well-known contraindication to restrictive bariatric procedures.[25] Patients were considered eligible after evaluation of clinical history, a thorough physical examination, blood chemistry, hormonal status, esophagogastroduodenoscopy, barium meal, esophageal manometry, 24-hour pH-metry, spirometry, and abdominal ultrasound (if cholelithiasis were present, a cholecystectomy was routinely performed at the time of bariatric surgery).

Multiple preoperative interviews were conducted with the patients with the goal of creating a clear understanding of expected benefits, risks, and long-term consequences of gastric restrictive procedures. This included establishing a clear representation of the anticipated postoperative changes in eating habits, necessary behavior modifications, and requisite prolonged follow-up with nutritional counseling and testing. A special consent form signed by the patient was also required for trial inclusion.

Surgical Techniques

LASGB

The LapBand (Bioenterics, Carpinteria, CA) was used in all patients. The patient was placed in a steep reverse Trendelenburg position. The laparoscopic procedure was carried out through five operative ports positioned in the upper abdomen, after insufflation was achieved in all cases with a Veress needle inserted in the left hypochondrium. The calibration tube (Bioenterics) was passed transorally by the anesthetist into the stomach. Twenty-five milliliters of saline was added to the balloon, and the tube was gently withdrawn from the mouth until the balloon seated at the gastroesophageal junction.

Dissection of the retrogastric tunnel commenced at a point on the lesser curve level with the equator of the balloon. Dissection was performed with an articulating dissector, close to the gastric wall, and carefully maintained above the lesser sac. Once the left diaphragmatic crus was reached, the LapBand was introduced through a 15-mm port and the end plug placed in the dissector slot. While the balloon was inflated with 15 mL of saline, the band was positioned and locked to calibrate the pouch. To keep the band in place, four seromuscular nonabsorbable sutures were placed between the pouch and the anterior gastric wall immediately below the band. The tubing was connected to the access port positioned subcutaneously in the left upper abdomen, and the band was left deflated at the end of the operation.

LVBG

The patient was placed in a steep reverse Trendelenburg position. The operation was performed through six ports. Laparoscopic dissection started on the lesser curvature of the stomach at 6 cm from the gastroesophageal junction. At this level, the lesser omentum was progressively dissected close to the stomach wall to gain access to the lesser sac. A 2-cm window was developed.

The transgastric window was then created. A 12-mm diameter calibrating tube was introduced into the stomach and grasped with an Endobabcock (Tyco HealthCare, Auto-Suture Company, United States Surgical Corporation, Norwalk, CT) along the lesser gastric curve to serve as a guide for calibration of the outlet. The 15-mm port in the right upper abdomen was withdrawn and a 21-mm-diameter circular stapler (ECS 21, Ethicon Endosurgery, Cincinnati, OH) was inserted percutaneously. The stapler penetrated the lesser sac via the window along the lesser gastric curve. Both gastric walls were perforated by the stapler prior to mating with the anvil and firing of the stapler. An Endo-GIA stapler (Tyco HealthCare) 60 mm in length, using 4.8-mm staples, was inserted through the gastric window and directed toward the angle of His. The calibrating tube was kept in place along the lesser curve. Typically, two stapler cartridges were necessary to complete the pouch.

All staple lines were carefully inspected. Bleeding vessels were suture-ligated with polypropylene sutures and extracorporeal knotting. Finally, a polypropylene mesh band was premarked. It was wrapped flat around the gastric pouch outlet and sutured to itself to create a 5-cm circumference to calibrate the gastric pouch outlet.

Outcome Assessment

All patients underwent an upper gastrointestinal evaluation with hydrosoluble contrast medium on the first (LASGB) or on the second (LVBG) postoperative day.

Follow-up visits, clinical evaluations, and blood tests were scheduled every 3 months during the first year, annually thereafter. Twenty-four-hour pH-metry and esophageal manometry were performed at 3 and 12 months postoperatively. An upper gastrointestinal series with barium meal and a gastroscopy were typically carried out at 1 and 3 years postoperatively and in the case of clinical symptoms or nonsatisfying weight loss. Unsatisfactory weight loss was defined as weight loss at 3 months <20% of excess body weight loss (EWL), at 6 months <30% EWL, or at 1 year and after <40% EWL. In cases of unsatisfactory weight loss following LASGB, a band recalibration was performed by inflating the band with 1 to 1.5 mL saline under fluoroscopic control; a clinical examination was scheduled 20 days after each band recalibration.

The following data were recorded: surgical time (time between skin incision and closure of the wound), anaesthesiology time (global time in the operative room), conversion rate, intraoperative and postoperative morbidity, 60-day mortality, and length of hospital stay. Long-term complications, additional procedures, readmissions, and hospital stay were also evaluated. Percentage of EWL, Reinhold classification,[26] and residual BMI were used to describe the postoperative results. Ideal weight was determined by the use of Metropolitan Life Insurance Company tables.[27] The results were expressed as excellent when the patient had 0% to 25% excess weight, a good result was 26% to 50%, a fair result was 51% to 75%, a poor result was 76% to 100%, and a failure was >100% excess weight at the time of evaluation.

Statistical Analysis

The primary endpoint of the study was reoperation rate. Secondary endpoints were early and late complication rates, and percent EWL at 1, 2, and 3 years. Appropriate sample size was calculated based on assumption of a difference of 5% in the reoperation rate between LASGB and LVBG, a difference of 5% in early and late complications, and a difference of 10% in percent EWL. These differences were considered clinically significant, and a sample size of 100 patients (50 in each group) was needed to prove these differences. Randomization was performed 1 day before surgery by means of sealed opaque envelopes containing computer-generated random numbers. Categorical variables were compared by χ^2 test, with Yates correction and the Fisher exact test (two-tailed) when necessary. Continuous variables were compared by the Student *t* test or the Mann-Whitney *U* test, depending on distribution. All *P* values were two-sided. A *P* value of <0.05 indicated a statistically significant difference. All calculations were done with SPSS (version 10.0).

RESULTS

Between February 1999 and December 2000, 175 patients were submitted to bariatric surgery at our institution; 75 (42.8%) were excluded from the study because of: BMI >50 kg/m^2 (35 patients), BMI <40 kg/m^2 with comorbidities (5 patients), specific contraindication to pneumoperitoneum (4 patients), previous gastric surgery (6 patients), severe reflux disease (14 patients), and refusal to enter the protocol (11 patients).

A total of 100 patients were randomized to either LASGB (n = 49) or LVBG (n = 51). The two groups were comparable in sex, age, mean weight, BMI, percent EW, and laboratory test results (Table 1). An associated procedure was performed in 10% of both groups. Four cholecystectomies and one lymph node biopsy were performed in Group A. Five cholecystectomies were performed in Group B. There were no deaths or conversions to open surgery in either group. The mean operative time was significantly longer in the LVBG group versus LASGB: 94.2 minutes (range 40–270 minutes) versus 65.4 minutes (range 35–120 minutes) ($P < 0.05$). Early postoperative morbidity was less frequent in the LASGB group (6.1%) versus LVBG (9.8%), but it did not reach statistical significance ($P = 0.754$) (Table 2). There was one early postoperative band slippage in LASGB, on postoperative day 7. It was treated by laparoscopic reposi-

TABLE 1. Patient Demographic Data

	N	Sex	Age (yr)	Weight (kg)	BMI (kg/m^2)	% EW
Group A (LASGB)	49	F 38	37.2	121.5	44.7	106.5
		M 11	(20–55)	(90–175)	(40.1–50.0)	(79.3–142.6)
Group B (LVBG)	51	F 43	38.2	118.7	44.2	104.8
		M 8	(21–58)	(90–160)	(40.0–50.0)	(79.4–136.0)

LASGB, laparoscopic adjustable silicone gastric banding; LVBG, laparoscopic vertical banded gastroplasty; BMI, body mass index; %EW, percentage of excess weight.

TABLE 2. Operative Results and Complication Rate

	N	Operative Time (min)	Hospital stay (days)	Mortality (%)	Conversion (%)	Early Morbidity (%)	Late Complications (%)	Late Reoperations (%)
Group A (LASGB)	49	65.4 (35–120)	3.7 (2–6)	0	0	6.1	32.7	24.5
Group B (LVBG)	51	94.2 (40–270)	6.6 (3–58)	0	0	9.8	14	0
*P**		<0.05	<0.05			0.754	<0.05	<0.001

LASGB, laparoscopic adjustable silicone gastric banding; LVBG, laparoscopic vertical banded gastroplasty.
*Two-sided $P < 0.05$ indicates a significant difference.

tioning. Also, there was one port infection and one hematoma at the port site.

In the LVBG group, we experienced one fistula at the staple line diagnosed at the second postoperative day and treated with open gastric bypass. There were two cases of prolonged postoperative pyrexia that resolved with nonoperative treatment. Two respiratory failures, without evidence of pulmonary embolism, resolved with conservative therapy. Therefore, one patient in each group underwent an early reoperation.

Mean length of hospital stay was shorter in the LASGB group (3.7 days) versus LVBG (6.6 days), which was statistically significant ($P < 0.05$) (Table 2). All patients underwent a minimum follow-up of 2 years: mean 33.1 months (range 24–46 months). Patients present at follow-up were: 98% at 1 year, 94% at 2 years, 90% at 3 years in the LASGB group and 90%, 88%, and 95%, respectively, in the LVBG group.

Concerning long-term complications and reoperations following these operations, LVBG was superior to LASGB. Late complications in LVBG were seen in 14% (7 of 50) of patients versus 32.7% (16 of 49) in LASGB patients. This was statistically significant ($P < 0.05$). Late reoperations in LVBG were not required (0 of 50) while 24.5% (12 of 49) of the LASGB group required another operation. Again, this was statistically significant ($P < 0.001$). In the LVBG group, complications included one pouch dilatation, an asymptomatic pouch-to-fundus fistula, four symptomatic reflux diseases, and a gastric bezoar. Again, no reoperations were performed in the LVBG group.

In the LASGB group, there were nine cases of gastric band slippage, three patients with symptomatic reflux diseases, one patient suffered complete food intolerance, one poor compliance, one port was infected, and one port twisted. There were 12 reoperations performed in the LASGB patients. Eight bands were removed (in six cases for slipping, in one case for severe reflux esophagitis, in one case for poor compliance; in two cases a LVBG was performed). One band slipped was laparoscopically replaced, one patient underwent a gastric bypass because of food intolerance without complications related to the band, one port was repositioned, and one port was removed.

Finally, LVBG was significantly superior to LASGB in terms of weight loss as shown in Figure 1. If we consider results according to Reinhold's classification, an excellent or good result (residual excess weight < 50%) was achieved at 2 years in 35% of LASGB and in 74% of LVBG ($P < 0.001$); at 3 years in 25% of LASGB and in 63% of LVBG ($P = 0.056$). Procedural failure resulting from insufficient weight loss (residual excess weight >100%) was present in 5% and

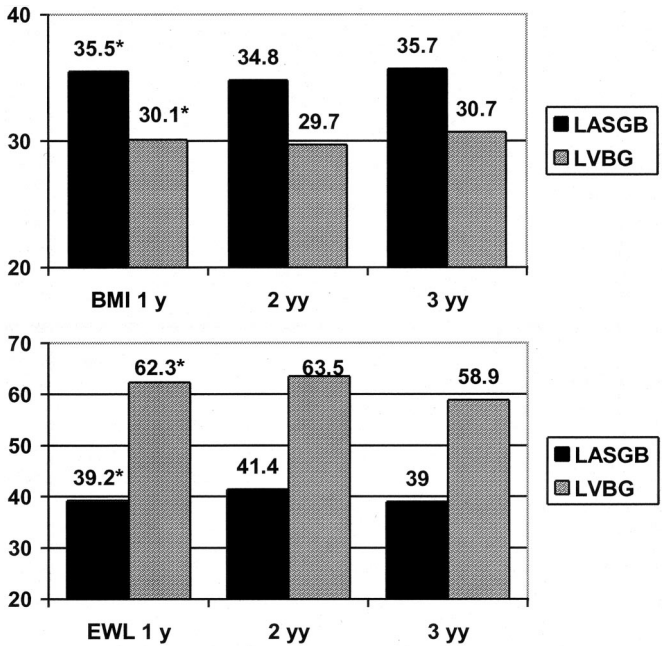

FIGURE 1. Results on weight loss in the two randomized groups of patients that underwent laparoscopic adjustable silicone gastric banding (LASGB) or laparoscopic vertical banded gastroplasty (LVBG) expressed in terms of residual body mass index (BMI) and percentage of excess weight loss (EWL) at 1, 2, and 3 years of follow up (*$P < 0.05$).

6% at 2 and 3 years in the LASGB patients, while no failures were seen in the LVBG group.

DISCUSSION

In recent years, a minimally invasive approach has become the preferred technique for bariatric surgery. Explanations for this trend include several advantages related to less postoperative discomfort and reduced surgical risk for obese patients. All bariatric procedures are now routinely performed laparoscopically. Beginning with LASGB[11–13] and LVBG,[24,28,29] followed by gastric bypass,[1,2,3,30] duodenal switch,[31] and biliopancreatic diversion,[32,33] the laparoscopic approach has gradually replaced the corresponding traditional open operations. A limited number of prospective studies and randomized trials have compared the open technique with the minimally invasive approach for the same operation.[21–23] There are no studies comparing different laparoscopic bariatric procedures.

In Europe, the tumultuous development of LASGB was based on the simplicity and feasibility of the technique with an excellent immediate postoperative course.[14–16]. However, there is limited availability of midterm and long-term results. Moreover, no clinical comparisons have been reported in the literature between an innovative procedure like LASGB and other restrictive bariatric procedures.

Recently, some concern has arisen regarding the efficacy of restrictive gastric procedures as therapy for morbid obesity.[25,34,35] For this reason, the majority of U.S. surgeons have leaned toward malabsorptive procedures or mixed restrictive and malabsorptive procedures. However, gastric restrictive surgery remains prominent in Europe. Success of these procedures in Europe is probably due to the different diet habits and to a lower mean BMI of European bariatric patients addressed to surgery.

We began the present study with purpose of comparing LASGB with the LVBG involving a complete transection of the stomach. Vertical banded gastroplasty was the bariatric restrictive procedure of choice at the time, before the advent of laparoscopy.[36] We were successful in obtaining excellent results with the laparoscopic approach[24] and have subsequently focused on the comparison of these two laparoscopic procedures.

Following its introduction, the technique of LASGB underwent several modifications.[37] Recently, different models of restrictive bands have been developed. At the time of our study, two models of bands were available: the heavily favored LapBand and the Swedish band (Obtech, St. Anton, Switzerland). For this reason, we decided to use the LapBand in the present study. It is noteworthy that the LapBand is the only model of gastric restrictive band currently approved by the Food and Drug Administration for clinical use.

Regarding LVBG, we used the technique previously described, transferring the Mason's classic technique[38] to the laparoscopic approach.[24] We modified the procedure as described by McLean et al,[36] with complete transection of the stomach. This avoids gastrogastric fistulas along the longitudinal gastric staple line, which leads to failure.

Our study demonstrated the feasibility and reproducibility of both procedures with a laparoscopy-to-open conversion rate of 0% in both groups. LASGB was significantly shorter, with a mean operative time of 65 minutes versus 94 minutes for LVBG ($P < 0.05$). Both procedures were safe without mortality. However, LASGB had inferior morbidity, although this did not reach statistical significance (6.1% vs. 9.8%; $P = 0.754$). The need for early reoperation rate was the same in both groups. Shorter operative time, lower morbidity, and a smoother postoperative course led to shorter mean length of hospitalization in the LASGB group (3.7 vs. 6.6 days with $P < 0.05$). These comparatively lengthy mean hospital stays were due to Italian health care system management. They were not related to problematic postoperative episodes except for the patient who developed a postoperative fistula after LVBG with a prolonged hospital stay of 120 days. Actually, these mean lengths of stay are half of those previously recorded in our country for patients undergoing the same surgery with an open approach.[39]

Early outcomes of this study confirm similar results reported in the literature for single center studies.[14–16,22,40] It's important to underline that to safely perform LVBG and LASGB the surgical team should have not only a good experience of advanced laparoscopic surgical techniques, including suturing and stapling, but also a good experience in open bariatric surgery and in the perioperative management of bariatric patients.

Based upon midterm and long-term results, LVBG is significantly superior to LASGB. LVBG has lower morbidity (14% vs. 32.7% with $P < 0.05$), reoperative rate (0% vs. 24.5% with $P < 0.001$), and more successful weight loss. Nilsell et al,[19] in their randomized trial on open adjustable banding and VBG, found different results, with a lesser weight loss and more reoperations following VBG, but gastroplasties were performed according to the original Mason technique,[38] with 18.5% of staple line disruptions. These complications were probably the reason of unsatisfactory results on weight loss and consequent reoperations; furthermore, the use of silicone collars could lead to a high percentage of outlet stenosis and reoperations.[41]

In our study, late slippage of the gastric restrictive band represents the most common problem as seen in 9 cases (18%). For specific purpose of reducing band slippage, the technique of LASGB underwent several modifications during the time. Specifically, Favretti et al[37] and Belachew et al[42] proposed placement of the band above the bursa omentalis and suturing it with four or more gastrogastric knots reducing the slippage rate from first reports of ≥50%[17] to a range of 5% to 21%.[14–16,42,43] All bands in this trial were positioned according to this technique. Some authors suggest a long

learning curve is the most likely culprit for band slippage. O'Brien et al[16] report a slippage rate of 12.5% during the first 350 cases and only 1% in the following 350 cases. All bands in our trial were placed by the same surgeon (M.M.) with a previous experience of more than 5000 laparoscopic procedures, 300 laparoscopic bariatric procedures, and 40 LASGB; if a longer learning curve is required, very few surgeons will be able to complete it.

We did not experience erosion of the gastric wall, a complication reported by several authors at a rate of 1% and 3%.[16,37]

In the effort to further reduce late complications, new models of the gastric band have been recently developed, for which there are no results reported in literature.

In terms of weight loss, LASGB results were not satisfactory at the 1-, 2-, or 3-year intervals (Fig. 1). Different weight loss outcomes following LASGB are reported in the literature. Several authors report results similar to this study[7,14,15] with a resulting BMI at 3 years of 33 to 36 kg/m^2. On the other hand, some series report better outcomes[40,44] with a resulting BMI around 30 kg/m^2. The main difference of these studies seems to be the selection of the patients. Restrictive gastric surgery is more efficient in mildly obese patients, rather than the superobese patient population. In studies with the best results,[40,44] the preoperative average BMI was 42 to 43 kg/m^2. In studies with the poorest results, initial BMI was 44 to 46 kg/m^2.[7,14,15] Moreover, studies with better results[40,44] stress diligent and meticulous follow-up with an intense program of alimentary education for LASGB patients. Therefore, the data from our randomized trial provide significant insight. Two groups of patients with the same preoperative BMI, with the same postoperative follow-up, demonstrated a greater weight loss in the group that underwent LVBG than those that underwent LASGB.

This study demonstrates that in a carefully selected group of European patients, nonbinge and nonsweet eaters with an initial BMI limited to 40 to 50 kg/m^2, restrictive surgery can have good results using LVBG but not LASGB. We have previously demonstrated that in patients with a BMI $>$ 50 kg/m^2, even LVBG provides disappointing long-term results.[24] We suspect a more complex procedure, such as gastric bypass, is required in these patients.

CONCLUSION

This study confirms that restrictive procedures, in particular LASGB, are safe. At the same time, it emphasizes the superiority of LVBG with less morbidity and better weight loss. It also confirms concerns of some authors[13,45] regarding the uncontrolled spread of the gastric banding without verification of the long-term outcomes. Its use was supported by technical feasibility and the benefits of a minimally invasive approach. Following the release of data summarized in this article, we have decided to suspend the routine clinical application of the LASGB. Its use is now limited to selected patients in which the advantages of a less complex and totally reversible procedure are the factors determining the choice of the surgical technique (eg, high anesthesiological risk, and BMI between 35 and 40 kg/m^2).

ACKNOWLEDGMENTS

The authors thank Don Selzer, MD, Department of Surgery, Mount Sinai Minimally Invasive Surgery Center, New York, NY, for revising the manuscript and Riccardo Ragona, MD, Department of Radiotherapy, University of Turin, Italy, for his help with the statistical evaluation of data.

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Discussion

DR. H.W. TILANUS: Thank you very much. I enjoyed your paper, but I still have a couple of questions. The first question is: is there a special way to put the Veress needle into these very obese patients? And the second question is: do you need a polypropylene mesh? My last question regards the long-term results because we have now only the early and 2- and 3-year results. I think in the long-term one of the major problems is the development of malabsorption syndrome as described in patients after gastric bypass.

DR. M. MORINO: I agree that it is sometimes difficult to perform pneumoperitoneum in bariatric patients. We use the standard Veress needle in the large majority of patients, but sometimes we use a visual trocar to enter the peritoneum. Concerning the mesh, in this study we have used a polypropylene mesh, the very same mesh that we were using in open surgery. Different studies concerning open VBG have compared different materials and shapes for the calibrating mesh, concluding that a polypropylene mesh 5 × 1.5 cm is the best mesh in terms of effectiveness and long-term results.

Your question on long-term results is important; on the very long period, restrictive procedures have all the same problem: some patients tend to regain weight. But this study was aimed to compare two restrictive procedures, so the problem will be, in my opinion, similar in both groups. Both procedures do not cause malabsorption either in the short term or later on. Nevertheless, it is our experience that at 5 years the results of VBG are still good, while some patients gain weight between 5 and 10 years from surgery. This is why recently there is a tendency to increase the indications to gastric bypass or malabsorptive procedures.

DR. A.G. JOHNSON: May I congratulate you on a beautifully designed study and power calculations before you started; that is excellent.

What surprised me was that you kept the patients after VBG in so long, ie, 6.5 days. I only keep my open VGBs in that length of time, so it does not seem that you have taken advantage of the less invasive approach. Why should there be a big difference between the two groups if they are both done laparoscopically?

DR. M. MORINO: I'm aware that a patient in the United Kingdom or United States is usually dismissed on the second or even the first postoperative day after laparoscopic bariatric surgery. Nevertheless, our attitude tends to be more conservative concerning hospital stay: we perform a water-soluble x-ray control during the second postoperative day in the LVBG group and on the first postoperative day in the LASGB group, and the patient leaves the hospital 1 or 2 days later.

Therefore, the difference in hospital stay between the two groups is a consequence of a 24-hour delay in performing the x-ray control and of a higher rate of complications in the LVBG group. Furthermore, the mean hospital stay in the LVBG group is influenced by the only severe complication in both groups: a fistula necessitating a reoperation on the second postoperative day and an overall hospital stay approaching 2 months.

DR. P.A. CLAVIEN: This is a very nice study comparing the two most widely used restrictive procedures to treat morbid obese patients. I have two questions. You included only patients with a BMI between 40 and 50. While most bariatric surgeons currently perform a restrictive procedure in this population, they prefer a malabsorptive procedure in those with a BMI above 50. Would you consider similar studies using a restrictive procedure in those with a higher BMI? Second, what would be your next study? Since you have initiated this study in 1999, we have gained wide experience with laparoscopic gastric Roux-en-Y bypass, including low complications rates. Would you consider to compare your best restrictive procedure, ie, vertical gastric banding, with laparoscopic gastric Roux-en-Y bypass in patients with a BMI between 40 and 50?

DR. M. MORINO: We follow the indications to bariatric surgery that were defined at the Consensus Conference of Bethesda, in 1991: a BMI over 40 or between 35 and 40 when the patient has comorbidities. We never operate on a patient with a BMI between 30 and 35. We are very strict in indications, and I would like to stress the medicolegal issue in bariatric surgery. This is a very delicate surgery on the side of medicolegal issues and surgeons should be extremely cautious with patient selection. Maybe that in the future, due to the good results of laparoscopy, the indication will be enlarged, but for the moment we maintain the same indications as in open surgery.

DR. J. PERISSAT: Mr. Chairman, Dear Colleagues: There is no doubt that the laparoscopic approach has completely rejuvenated the bariatric surgery. It deletes all the complications linked to laparotomy, that is, on obese people, the addition of new sources of morbidity even mortality.

But we have not yet clear ideas about the choice of the various proposed procedures.

Professor Morino provides us, for the first time as far as I know, a document of highest level of evidence, able to guide our choice between the two major so-called "restrictive" procedures. I share completely his conclusion. But I do not think that we have to give up the use of gastric banding placement. Professor Morino omits in his presentation and abstract (I did not have the opportunity to read the entire paper) to outline that the gastric banding is a quite easy reversible procedure also by laparoscopic approach. This is not the case for the Mason one. Easy to replace and retrieve, having immediate excellent results on weight loss but not so good long-lasting ones, the banding could be inserted in a new strategy for obesity cure. It could become a tentative operation enabled to have a quick weight loss relayed in case of obesity beginning of recurrence by more long-term successful procedures, such as gastric bypass or other so-called "nutritional effect" operations.

I would like to know the opinion of Professor Morino on that.

Mr. Chairman, let me thank you to give me the privilege to comment on this presentation. I appreciate it very much. It comes from one of our main new leaders in Laparoscopic Surgery.

DR. M. MORINO: Thank you Professor Perissat for your comments.

First about reversibility: the Mason technique is reversible. You can staple together with a linear stapler the two pouches leaving in place the prolene mesh. By doing so, you will lose every restrictive effect and the patient will eat normally. The band is easier to remove, but we do not choose a procedure because it is easy to take down. The problem with bariatric surgery is that if you do a reverse procedure, the patient will go back to his or her eating habits and will progressively gain weight.

Concerning your comment on the use of the band as a tentative operation to verify if the patient will lose weight with a restrictive procedure, we prefer to use the endoscopic intragastric balloon in this setting. When we are not sure that the patient will have a good result with the restrictive procedure, we use flexible endoscopy to put in place an intragastric balloon. The patient will have the balloon for 4 to 6 months: if he or she loses weight with the balloon, we will go on with another restrictive procedure that is LVBG: on the contrary, if the balloon is not effective, we will propose to the patient a laparoscopic gastric bypass.